

Attorney Docket No.: LVIP:106US
U.S. Patent Application No. : 10/604,135
Reply to Office Action of February 23, 2006
Date: April 24, 2006

Remarks/Arguments

In the Office Action issued February 23, 2006, the Examiner objected to the amendments to the disclosure filed December 5, 2005 as new matter. Specifically, Figure 8 and paragraph [0022A] which were added to the disclosure were deemed new matter that was required to be canceled in the reply to the Office Action. Applicants respectfully submit that the subject matter contained in Figure 8 and paragraph [0022A] are not new matter and request that the objection be reversed. Applicants are intent on petitioning the Director if this Request for Reconsideration is unsuccessful in vacating the new matter objection to Figure 8 and paragraph [0022A]. For that reason Applicants request that this Request be handled with all due speed.

Objections to the Drawings

In the Office Action issued on September 27, 2005 the Examiner objected to Figure 1 for failure to designate the figure as prior art. In the Reply filed on November 30, 2005 Applicants followed the Examiner's instruction and amended Figure 1 to recite "Prior Art" in the legend. The replacement sheet was located in the Appendix. No new matter was added. Reversal of the objection was courteously requested, however, the Examiner did not acknowledge this submission in the Office Action issued on February 23, 2006. Applicants again courteously request that the Examiner withdraw the objection.

Objection to Figure 8

The Examiner rejected the new Figure 8 that was submitted in the Reply filed on November 30, 2005 because it was deemed to introduce new matter into the disclosure. Every element illustrated in Figure 8 is specifically described and fully enabled in the original written description of the instant patent application. Therefore, Applicants respectfully request that the objection for adding new matter be withdrawn.

Incident illumination system

In paragraph [0017] and in Figure 2 of the original disclosure it is explicitly demonstrated and described how an incident illumination system is arranged and provided. The light emitted

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from the illumination system 20 is directed toward a water-filled collection pan. The light is then reflected from this collection pan on an optical axis to an observation microscope. In paragraph [0020] and Figure 5 the exemplary embodiment of the invention is shown using diodes reflecting light off a collection pan similar to that used in Figure 2. It is clearly depicted in Figure 2 and 5 that a knife has a collection pan positioned on its front side. Both of these figures and their accompanying description in paragraph [0017] and [0020] give ample description and support as to how the incident illumination is provided on the claimed microtome.

Base-mounted illumination system

In paragraph [0018] and [0019] and in Figure 3 and 4 there is a detailed description of the arrangement and function of the base-mounted illumination system. Light emitting from the base-mounted illumination system is directed upward toward the knife and then reflected by knife toward the preparation on the specimen arm (See Figure 3). The gap between the knife and the preparation is bright and allows the user of the microscope to observe the position of the preparation relative to the knife. The combination of paragraphs [0018] and [0019] and the drawings in Figure 1 and 3 from the original description, clearly demonstrate to one skilled in the art how the base-mounted illumination system is to be positioned on the microtome and fully support the assertion that the application discloses a microtome with a base illumination system.

Internal preparation illumination system

In paragraph [0021] and Figure 7 there is ample description and demonstration to enable one skilled in the art to provide an internal preparation system on a microtome. In paragraph [0021], the internal preparation illumination system is described as a light-emitting diode provided in the specimen arm behind the preparation. The power for the diode is provided by electrical cables that are guided through a continuous open tube in the specimen arm. After reference to Figure 1 it is apparent how the internal preparation illumination system, which is housed in the specimen arm, is positioned on the claimed microtome. The written description and drawings clearly support the assertion that an internal preparation illumination system on the claimed microtome is disclosed and fully described in the application.

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Combination of the three illumination systems

With the description of the location and arrangement of the three separate illumination systems detailed above, combined with the explicit instruction that the three systems are combined in a single microtome, there is certainly ample support for the new Figure 8. It is explicitly stated in paragraph [0017] and [0018], that several parts of the microtome are omitted from drawings in order to focus on the essential parts of the invention, and to provide more detail on those separate illumination systems. Hence, the only reasonable conclusion that can be drawn from the specification is that the three illumination systems are shown separately in order to focus on the parts of the three separate illumination systems. This explains why the focused drawings of the individual illumination systems are not shown combined on a single microtome. The instant written description supplies ample detail and description of the three illumination systems to enable one of ordinary skill to make and use the three illumination systems. Once understanding the placement and operation of the three separate illumination systems, one of ordinary skill in the art would be capable of combining the three illumination systems in a single microtome based on the instruction the written description to do just that. In paragraph [0012], the microtome is described as having: a knife, a specimen arm movable relative to the knife, and at least one light source acting as a base-mounted illumination system, at least one light source acting as an incident illumination system, at least one light source acting as an internal preparation illumination system. Clearly this states that there are three separate illumination systems on one microtome. Most importantly, paragraph [0012] goes on to clarify that all illumination systems illuminate a region around the preparation. Consequently, there is ample support for a microtome with three illumination systems as described above. There is also sufficient support in the above referenced paragraphs and figures originally provided, to understand the relationship of the three illumination systems and how they are provided at the same time. By adding Figure 8, the original drawings have merely been blended into a single drawing to encapsulate what paragraph [0012] and Claim 1 of the original specification already explicitly state, i.e., that the microtome is comprised of three separate illumination systems at once. Paragraphs [0019], [0020], and [0021] are support for the individual structures as shown in

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new Figure 8. Paragraph [0012], which describes a microtome having three separate illumination systems, is support for new Figure 8 that depicts the combination in a single microtome. Hence, Applicants respectfully submit Figure 8 and paragraph [0022A] are supported by the specification and no new matter has been added.

Assuming that paragraphs [0012] and [0017] - [0021], and Figures 1-7 do not provide ample support for the new Figure 8 and paragraph [0022A], which they most certainly do, Applicants respectfully submit that “subject matter not shown in the drawing or described in the description is claimed in the application as filed, and such original claim itself constitutes a clear disclosure of this subject matter, then the claim should be treated on its merits, and the requirement made to amend to amend the drawings and description to show this subject matter.” MPEP 608.01(l). Applicants submit that Claim 1 recites “a microtome or ultramicrotome having a knife, a specimen arm movable relative to the knife, a microtome having at least one light source acting as a base-mounted illumination system, at one light source acting as an incident illumination system, and at least one light source acting as an internal illumination system, and wherein all illumination systems illuminate a region around the preparation.” This claim does not recite that the one illumination system can be chosen to the exclusion of another anymore than it recites that the knife can be chosen to the exclusion of the specimen arm. The descriptive names of each illumination system and the drawings of the three separate illumination systems clearly describe the positioning of the individual illumination systems on the microtome. There would be no confusion to one of ordinary skill in the art how to make and use a microtome given just the claims. Thus the Examiner should permit the Applicants to amend the drawings and description to capture in more exacting detail what is specifically recited in Claim 1. The three illumination systems in a single microtome was originally claimed, therefore, the addition of Figure 8 and paragraph [0022A] is a permitted amendment to the drawings and description that should not be considered the introduction of new matter.

Although not necessary to enable the invention, Applicants have added a new figure, Figure 8, which combines the drawings in the existing Figures 3, 5, and 7 to further illustrate to the Examiner that the three illumination systems were described in the original application.

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Figure 8 combines already existing Figures 3, 5, and 7 into a single drawing to further illustrate that the microtome has three separate illumination systems provided at the same time. Paragraphs [0019], [0020], and [0021] support the new Figure 8 depicting the three individual illumination structures. Paragraph [0012], which describes a microtome having three separate illumination systems, is support for combining the three illumination systems shown in Figure 8. Hence, Figure 8 is supported by the original specification and no new matter has been added.

As shown in Figures 3, 5, 7, and 8, there are no structural conflicts among the three illumination systems. Each system is located in a different portion of the microtome and is not required to share substantive structural elements. Figures 3, 5, 7, and 8 also show that there is no conflict or interference among the light paths generated by the illumination systems.

Applicants request reversal of the objection.

Rejection of Claims 1-4, 10, and 11 under 35 U.S.C. 112, first paragraph; Written Description

The Examiner has rejected Claims 1-4, 10 and 11 under 35 USC 112, first paragraph, as failing to comply with the written description requirement. Applicants draw attention to the previous discussion addressing the “new matter” objection from the Examiner. The above discussion illustrates the ample written description that demonstrates that Applicants were in possession of the claimed invention at the time of filing. Applicants have added the new Figure 8 and paragraph [0022A] which combines the drawings in the existing Figures 3, 5, and 7, which only further demonstrates that the written description requirement has been met. Figure 8 combines already existing Figures 3, 5, and 7 into a single new Figure 8 to supplement the existing drawings which already fully support the description of a microtome that has three separate illumination systems existing with the microtome at the same time. Description of the invention can be found in places other than in just the written portion of the disclosure and “[a]n applicant [can] show possession of the claimed invention by describing the claimed invention with all of its limitations using descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claim invention.” MPEP §2163; *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997) (emphasis added). Figures 3, 5 and 7 combined with paragraph [0012] accomplish the task of reasonably conveying that the

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Applicants were in possession of the invention claimed, and that puts the public in possession of the invention that has been claimed. By adding Figure 8, the original drawings have merely been blended into a single drawing to encapsulate what Paragraph [0012] and Claim 1 of the original specification already explicitly state, i.e., that the microtome is comprised of three separate illumination systems at once. Paragraphs [0012], and [0017] - [0021] are support for the individual structures recited in claims 1-4, 10 and 11. Paragraph [0012], which describes a microtome having three separate illumination systems, is adequate written description for the combination of the three illumination systems in a single microtome. Hence, Claims 1-4, 10 and 11 are fully described in the description and drawings to inform the public that Applicants were in possession of the a microtome with three illumination systems that function simultaneously.

The Examiner also asserts that the specification does not convey that Applicants were in possession of the claimed invention because one of ordinary skill in the art would not decipher from the specification how the three illumination systems "each function over the other". Applicants submit that one of ordinary skill in the art would understand how the three illumination systems would function given the ample description in the "Background of the Invention" that details the function and use of prior art illumination systems (an indication that the level of knowledge relating to illumination system functioning is very high), coupled with the "Summary and Description of the Invention". The amended disclosure reasonably conveys to one skilled in the art that Applicants had possession of the claimed invention having three separate and distinct illumination systems combined in one microtome. Applicants request reversal of the rejection.

Rejection of claims 1-4, 10, and 11 under 35 U.S.C. 112, first paragraph; Enablement

The Examiner has rejected claims 1-4, 10, and 11 under 35 U.S.C. 112, first paragraph because the claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. The enablement requirement does not require that the information in the disclosure of an application contain details that would "enable one of ordinary skill in the art to make perfected, commercially viable

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embodiment absent a claim to that effect,” but that the information provided in the disclosure be sufficient to inform those in the relevant art to make and use the claimed invention. MPEP 2164; *CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 68 USPQ2d 1940, 1944 (Fed. Cir. 2003). In Paragraph [0012] it is explicitly stated that the microtome has “at least one light source acting as a base-mounted illumination system, at least one light source acting as an incident illumination system and at least one light source acting as an internal preparation illumination system, and wherein all said illumination systems illuminate a region around the preparation and all illumination systems encompass light-emitting diodes.” This paragraph clearly indicates that three separate illumination systems are all contained in one microtome. Paragraphs [0019], [0020], and [0021] further clarify how these three separate illumination systems operate, and the specification explains the structure and function of each illumination system separately for clarity. Also in Paragraphs [0017] and [0019] it is mentioned that for the sake of clarity several parts of the microtome are omitted in the individual figures. This was done to clearly demonstrate that the illumination systems are separate elements contained in one microtome. Never does the specification contradict the explicit instruction that all three illumination systems are to be contained in one microtome. The detailed images of the separate illumination systems juxtaposed with Figure 1, which depicts the microtome, illustrate how a microtome would function with the three illumination systems separately described.

Figure 1 and 2 give ample information to enable one skilled in the art to understand where the incident illumination system is placed on a microtome. Also, one of ordinary skill in the art would understand that a specimen arm, which houses the internal preparation illumination system, would be located on the microtome in front of the knife. With that knowledge one of ordinary skill would be enabled to understand the location of the internal preparation illumination system. A skilled artisan would also know where the claimed base-illumination system would be placed because Figure 3 shows not just the illumination system but also the specimen arm and knife. From the information in Figure 3 and Figure 4 and the accompanying written description one of ordinary skill in the art would be enabled to make the combination claimed.

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Applicants submit that these passages clearly convey to one skilled in the art that three separate illumination systems are to be combined, and the accompanying Figures 7 (showing an internal preparation illumination system), 5 (showing an incident illumination system), 3 (showing a base-mounted illumination system) demonstrate the structure of the three separate illumination systems and how they would be combined on a single microtome. By examining the existing drawings and their corresponding descriptions in the specification one of ordinary skill in the art would understand the proper placement of the three illumination systems in relation to each other on the microtome.

Applicants have also added Figure 8 as a supplemental drawing to address the enablement rejection. Paragraphs [0019], [0020], and [0021] support the individual structures as shown in Figure 8, and also Paragraph [0012], which describes a microtome having three separate illumination systems, is support for the combination on a single microtome. Hence, Figure 8 is supported by the specification and is not new matter and should be considered further information that would enable one skilled in the art to make and use the invention recited in Claims 1-4, 10 and 11. Applicants respectfully submit that the application clearly shows in the original drawings, the specification, and newly added Figure 8 and paragraph [0022A] how to make a microtome with the three illumination systems claimed and how to use a microtome with respect to the functioning of one light source over another. Applicants submit the Examiner appears to expect a greater degree of description than is statutorily required. The original drawings and specification sufficiently indicated the positioning of the illumination systems in relation to the microtome. By referring to Figures 3, 5, 7, and also 8, one of ordinary skill in the art could determine how to make and use the claimed invention. Applicants request reversal of the rejection.

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Rejection of Claims 1-4, 10, and 11 under 35 U.S.C. 112, second paragraph

The Examiner rejected Claims 1-4, 10, and 11 under 35 U.S.C. 112, second paragraph as being indefinite. The Examiner reiterates a similar argument used to reject Claims 1-4, 10, and 11 under 35 USC 112, second paragraph for this rejection of the same claims under 35 USC 112, second paragraph, i.e., "it is not clear how each of the illumination systems can be provided at the same time."

35 USC 112, second paragraph, requires that 1) the claims to set forth the subject matter that applicants regard as their invention; and 2) the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant. See MPEP 2171. Applicants respectfully submit that Claims 1-4, 10 and 11 have clearly defined the boundaries of their invention and thus have met the requirements of 35 USC §112, second paragraph. For instance in Claim 1, it recites that the main elements of the microtome are a knife, a movable specimen arm, an internal preparation illumination system, an incident illumination system, a base-mounted illumination system, "wherein all said illumination systems illuminate a region around the preparation and all illumination systems encompass light-emitting diodes." Claim 2-4, 10 and 11 each recite similar language that with clarity and precision recites what is claimed. The Examiner has expressed that since it is not clear how each of the illumination systems can be provided at the same time the claim language is indefinite. The issues surrounding the adequacy of the written description have been addressed above and those arguments further support the position that the claim language is definite. For the foregoing reasons, Claims 1-4, 10, and 11 are definite under 35 U.S.C. 112, second paragraph and Applicants request that the rejections be withdrawn.

Rejection of Claims 1, 10, and 11 under 35 U.S.C. §103

The Examiner rejected Claims 1, 10, and 11 as being obvious in view of the teachings of German Patent Application No. DE 32 24 375 (Bilek), German Patent Application No. De 36 15 713 (Wolf), and U.S. Patent Application Publication No. 2003/0024368 (Fukuoka).

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"[T]o establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some teaching, suggestion or motivation, either in the references themselves or in the knowledge generally available to one having ordinary skill in the art, to modify the references or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references (or references when combined), must teach or suggest all of the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure." MPEP §2142, citing *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir.1991) (emphasis added).

Claim 1

Claim 1 recites at least one light source acting as a base-mounted illumination system, at least one light source acting as an incident illumination system, and at least one light source acting as an internal preparation illumination system wherein the illumination systems comprise LED's and are configured to illuminate the region around the preparation.

Bilek does not teach an internal preparation illumination system or an incidental illumination system

The internal preparation system recited in Claim 1 provides light behind and through a specimen as shown in Fig. 7. The incident light illumination provides illumination between a blade and a specimen to visually accentuate the space between the blade and specimen, as shown in Fig. 3. Bilek does not teach the structure or functionality recited in Claim 1. Nor does Bilek suggest or motivate the above-mentioned limitations of Claim 1.

Wolf does not teach an internal preparation illumination system or an incidental illumination system

The internal preparation system recited in Claim 1 provides light behind and through a specimen as shown in Fig. 7. The incident light illumination provides illumination between a blade and a specimen to visually accentuate the space between the blade and specimen, as shown in Fig. 3. Wolf does not teach the structure or the functionality recited in Claim 1. Instead, Wolf teaches an unrelated optoelectrical means for detecting the position of a specimen. Wolf contains no teaching regarding the illumination of a specimen. Since Wolf is not addressing the problem

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of illuminating a specimen or visually accentuating a space between a specimen and a knife, Wolf does not suggest or motivate the above-mentioned limitations of Claim 1.

Wolf does not teach the use of LEDs in an illumination system

Wolf teaches the use of an LED as a position sensor: "The position sensor consists of a light-emitting diode (89)..." (Abstract). Wolf does not teach using an LED in an illuminating system.

Fukuoka does not teach an internal preparation illumination system or an incidental illumination system

Fukuoka does not teach a microtome and therefore, cannot teach the above-mentioned illumination systems or that such systems comprise LEDs.

There is no motivation to combine the cited references

"In order to rely on a reference as the basis for rejection of an applicant's endeavor, the reference must be either in the field of applicant's endeavor or, if not, be reasonably pertinent to the particular problem with which the invention was concerned." MPEP §2141.01(a) citing In re Oetiker, 977 F.2d 1443, 1446 (Fed. Cir. 1992). In the present case, Fukuoka is not analogous to the present invention; it is not in the field of Applicants' endeavor and is not reasonably pertinent to Applicants' problem. Specifically, the Applicants' invention comprises a microtome or ultramicrotome for preparing thin sections of samples for microscopy, typically frozen tissue sample. As such the illumination system of the present invention is adapted to minimize the formation and/or the emission of heat, since microtome illumination using incandescent bulbs would generate heat intensity that would affect the thickness of sample sections for use in microscopy. The heat generated by the light bulbs would cause a thermal expansion of mechanical elements of a microtome. The thickness of a slice from a sample is controlled by the relative motion of the knife with respect to the face of the sample. In order to assure a constant thickness of the sample slices the relative motion has to be absolutely constant. Any thermal expansion has a negative effect on the constant sample thickness. In order to avoid an uncontrolled thermal expansion one would use LEDs instead of light bulbs. This has not been recognized before Applicants' invention.

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Since uniformity and predictability in sample thickness of sample sections is important purpose of this invention, it should be equally important that a reference used in an obviousness rejection be at least related to that objective. Fukuoka on the contrary describes a device comprising a circular saw used to cut lumber. The Fukuoka reference in Paragraph [0023] describes that LEDs are used as a light source to prevent the overheating of the grip portion of the circular saw. Heat generated by the light source had no impact on the successful cutting of the lumber and the Fukuoka's motivation for choosing LEDs was not to minimize the lumber (or sample) temperature due to possible fluctuations in the cut thickness. Furthermore, a circular saw is not concerned with preparing thin tissue samples for microscopy, nor is such a device concerned with minimizing heat. Thus, Fukuoka is not analogous to the present invention, is not in the field of Applicants' endeavor, and is not reasonably pertinent to Applicants' problem. There is no reason proffered by the Examiner why a person of ordinary skill in the art, seeking to solve the problem of overheating sample for microscopy and possibly affecting sample section thickness, would be reasonably expected or motivated to look to circular saws. See MPEP §2141.01 (a) citing 977 F.2d 1443 (Fed. Cir. 1992).

The Examiner has not fulfilled the requirements for a prima facie case of obviousness

The Examiner summarized the rejection by stating the following. Applicants' comments are italicized in brackets: "Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a light-emitting diode, as disclosed by Wolf [*Wolf teaches an LED as a position sensor, not an illumination source*], on the Bilek device [*Bilek does not teach an internal preparation illumination system or an incidental illumination system. Wolf and Fukuoka do not cure this defect of Bilek*] in order to reduce heat generation, as disclosed by Fukuoka [*Fukouka is non-analogous. Further, there is no motivation to combine Fukuoka with Bilek or Wolf*]. None of the cited references teaches, suggests, or motivates an internal preparation illumination system or an incidental illumination system. None of the cited references teaches, suggests, or motivates an LED in an illumination system for a microtome.

For all the reasons noted above, Bilek, Wolf, and Fukuoka fail to meet the requirements to establish a *prima facie* case of obviousness with respect to Claim 1.

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Claim 10

Claim 10 was rejected on the same grounds as Claim 1. Applicants have shown that Claim 1 is patentable over Bilek, Wolf, and Fukuoka. Therefore, Claim 10 also is patentable over Bilek, Wolf, and Fukuoka.

Claim 11

Claim 11 was rejected on the same grounds as Claim 1. Applicants have shown that Claim 1 is patentable over Bilek, Wolf, and Fukuoka. Therefore, Claim 11 also is patentable over Bilek, Wolf, and Fukuoka.

Applicants courteously request that the rejections be removed.

Rejection of Claims 2 and 3 under 35 U.S.C. §103 (Obviousness)

The Examiner rejected Claims 2 and 3 under 35 U.S.C. §103(a) as being unpatentable over German Patent Application No. DE 32 24 375 (Bilek), in view of German Patent Application No. De 36 15 713 (Wolf), U.S. Patent Application Publication No. 2003/0024368 (Fukuoka), and further in view of U.S. Patent No. 6,195,016 (Shankle et al.).

Applicants have shown that Claim 1 is patentable over Bilek, Wolf, and Fukuoka. Shankle teaches an optical display sign and fails to cure the defects of Bilek, Wolf, and Fukuoka with respect to Claim 1. Therefore, Claim 1 is patentable over Bilek, Wolf, Fukuoka, and Shankle. Claims 2 and 3, dependent from Claim 1, enjoy the same distinction from the cited references.

Rejection of Claim 4 under 35 U.S.C. §103 (Obviousness)

The Examiner rejected Claim 4 under 35 U.S.C. §103(a) as being unpatentable over German Patent Application No. DE 32 24 375 (Bilek), in view of German Patent Application No. De 36 15 713 (Wolf), U.S. Patent Application Publication No. 2003/0024368 (Fukuoka), U.S. Patent No. 6,195,016 (Shankle et al.) as applied to Claims 2 and 3, and further in view of U.S. Patent No. 4,896,967 (Douglas-Hamilton et al.).

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Applicants have shown that Claim 1 is patentable over Bilek, Wolf, Fukuoka, and Shankle. Douglas-Hamilton teaches a motility scanner and fails to cure the defects of Bilek, Wolf, Fukuoka, and Shankle with respect to Claim 1. Therefore, Claim 1 is patentable over Bilek, Wolf, Fukuoka, Shankle, and Douglas-Hamilton. Claim 4, dependent from Claim 1, enjoys the same distinction from the cited references.

Conclusion

For the reasons set forth above, Applicants respectfully submit that the present application is in condition for allowance, which action is courteously requested

Respectfully submitted,



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CPM/TGM
Dated: April 24, 2006